

Dakai Liu et al.

Serial N .: 09/046,833

Filed: March 24, 1998

Page 4 (Amendment Under 37 C.F.R. §1.115 - December 7, 1998)

#### REMARKS

Claim 68 was previously pending in this application. This claim has been amended above. New claim 69-74 have been added above. Accordingly, claims 68-74 are presented for further examination on the merits.

The title of the invention has been changed to reflect the subject matter now being claimed. In the "CROSS-REFERENCE TO OTHER RELATED APPLICATIONS," a minor error relating to the filing date of the parent application has been corrected.

Claim 68 has been amended in two ways. First, in response to the Examiner's comments under the indefiniteness rejection (35 U.S.C. §112, second paragraph), an informality with respect to the Markush language has been corrected (the conjunction "or" has been changed to "and"). Second, the phrase "said nucleic acid component and said non-nucleic acid component being capable of forming a specific complex" has been inserted into the third and fourth lines of claim 68. Support for the latter is found in Applicants' specification, page 6, lines 1-5.

Commensurate with Applicants' complete and broad disclosure, new claims 69-74 have been added above. These new claims are directed to the following dependent embodiments: where the cell line is native to said viral vector (claim 69); the viral vector comprises a retrovirus (claim 70); the viral vector nucleic acid component is native to the vector (claim 71); the viral vector nucleic acid component is non-native to the vector (claim 72); and the packaging cell line expresses on its membrane a member selected from the group consisting of a receptor for the non-native viral vector nucleic acid component, a binding partner for the non-native viral vector nucleic acid component, and an absorption partner for the non-native viral vector nucleic acid component (claim 73).

It is believed that the foregoing new claims are fully supported by the original specification and do not constitute the insertion of new matter into Applicants' disclosure. Entry of the above amendments and new claims is respectfully urged.

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#### Sequence Listing Statement

Applicants and their attorney acknowledge the Examiner's comments regarding their sequence listing for this application. In response, Applicants wish to state that the sequence listing in their application is the same as that in the parent application, U.S. Patent Application Serial No. 08/822,963, filed on March 21, 1997. Furthermore, a paper copy of the sequence listing is being submitted herewith attached as Appendix A. The attached paper copy (Appendix A) is identical to the computer readable form (CRF) of the sequence listing submitted in the aforementioned parent application (Serial No. 08/822,963). It is respectfully requested that the CRF in the parent application be used to prepare a file for this offspring application.

#### Submission of Information Disclosure Statement

Applicants' attorney and his paralegal are presently retrieving articles that may be material to the examination of this application. As soon as the retrieval has been completed, the articles were be submitted to the Patent and Trademark Office and the Examiner in the form of an Information Disclosure Statement.

#### The Rejection Under 35 U.S.C. §102

Claim 68 stands rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Salmons et al. ["Targeting of Retroviral Vectors for Gene Therapy," Human Gene Therapy 4:129-141 (1993) or Smith [Annual Review of Microbiology 49:807-838 (1995)]. In the June 5, 1998 Office Action, the Examiner stated:

Applicants claim a packaging cell line for propagating a viral vector independent of a helper virus comprising a nucleic acid component (stably integrated into the cell genome) and a non-nucleic acid component introduced into the cell by transient expression, stably integrated expression, etc.

Salmons et al. (Human Gene Therapy, Vol. 4, 1993, pp. 129-141, see whole article, particularly pp. 133-135) and Smith (Annu. Rev. Microbiol., Vol. 49, 1995, pp. 807-838, see whole article, particularly pp. 821-823) both recite packaging cell lines for propagating a viral vector independent of a helper virus wherein said

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viral vector is stably integrated into the genome of the host cell, wherein the viral vector is composed of nucleic acid and non-nucleic acid (i.e. protein) components and wherein the non-nucleic acid portion are introduced into the cell by stably integrated expression or transient expression. Therefore, Salmons et al. and Smith both teach the claimed invention.

The anticipation rejection is respectfully traversed.

As indicated in the opening remarks of this paper, claim 68 has been amended to recite "[a] packaging cell line for propagating a viral vector independent of a helper virus, said viral vector comprising a nucleic acid component and a non-nucleic acid component, *said nucleic acid component and said non-nucleic acid component being capable of forming a specific complex, . . .*" It is respectfully submitted that neither the cited Salmons or Smith review articles discloses Applicants' instantly claimed feature wherein the nucleic acid component and the non-nucleic acid component are capable of forming a specific complex with each other, thus providing useful properties in accordance with the present invention. Such useful properties include, for example, localization to defined regions of a nucleic acid construct, reduction or elimination of potential interference with region segments in the nucleic acid constructs and controlled displacement of binding proteins from binding sites to remove or reduce potential interference with biological function and the release of functionally useful proteins in the cell. See page 6 of the specification, last seven lines of the text.

In light of the lack of identity between Applicants' instantly claimed invention and the two cited documents, reconsideration and withdrawal of the rejection under 35 U.S.C. §102 is respectfully requested.

The Rejection Under 35 U.S.C. §112

Claim 68 stands rejected under 35 U.S.C. §112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the Office Action (page 3), the Examiner stated that "[c]laim 68 is vague in that it recites improper Markush language. The members of a Markush group are linked by 'and' not 'or.'"

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In light of the above amendments to claim 68, it is believed that the indefiniteness rejection has been rendered moot. Reconsideration and withdrawal of the rejection under the second paragraph of §112 is respectfully requested.

Having overcome both grounds of rejection, an early indication as to the allowability of the present invention is respectfully sought.

\* \* \* \* \*

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**SUMMARY AND CONCLUSIONS**

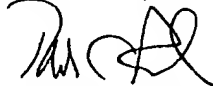
Claim 68-74 are presented above, dependent claims 69-74 having been newly added.

This Amendment is being accompanied by Applicants' Request For An Extension Of Time (3 months) and authorization for the fee therefor. No other fee or fees are believed due, including any claim fees. In the event, however, that any other fee or fees are due in connection with this Amendment, the Patent and Trademark Office is hereby authorized to charge the amount of any such fee(s) to Deposit Account No. 05-1135, or to credit any overpayment thereto.

If it would be helpful to expediting the prosecution of this application, the undersigned may be contacted by telephone at 212-583-0100 during the daytime business hours.

Early and favorable action on this application is respectfully sought.

Respectfully submitted



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Facsimile: (212) 583-0150

# APPENDIX A

## SEQUENCE LISTING

<110> Liu, Dakai  
Rabbani, Elazar

<120> VECTORS AND VIRAL VECTORS, AND PACKAGING CELL LINES FOR  
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